

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The effect of maternal empowerment program on the colostomy complications in infants and tolerance of mother's distress

Protocol summary

Study aim

Determining the effect of maternal empowerment program on infant colostomy complications and tolerance of maternal distress

Design

A clinical trial with two groups of intervention and control, parallel, randomized with 4 blocking method

Settings and conduct

Neonates admitted to Neonatal Surgery and Neonatal Intensive Care Unit at Akbar and Dr. Sheikh Hospitals receive maternal consent. The empowerment program for mothers in the intervention group is performed. Mothers in the control group receive routine care. Infants are examined one, two and three months later at the colostomy clinic and complications are assessed. The distress tolerance questionnaire is completed by the mother before and after the intervention.

Participants/Inclusion and exclusion criteria

infant 0 to 90 days age infants, both term and pre-term
Infant's stable clinical condition (including heart rate and respiration)
Need for colostomy in the treatment process
Lack of other abnormalities (such as metabolic diseases, immune deficiencies, and chemotherapy that affect colostomy symptoms).

Intervention groups

A 30- to 45-minute individualized empowerment program will be held to familiarize the gastrointestinal tract with problems and possible complications, cholestomy care and post-feeding and dressing. In addition, this intervention booklet is available to mothers in the intervention group.

Main outcome variables

Complications of skin cholestomy and complications leading to hospitalization
Tolerance of mother distress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191207045633N1**

Registration date: **2019-12-28, 1398/10/07**

Registration timing: **retrospective**

Last update: **2019-12-28, 1398/10/07**

Update count: **0**

Registration date

2019-12-28, 1398/10/07

Registrant information

Name

tahere peiravi dehsorkhi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

2019-03-21, 1398/01/01

Actual recruitment end date

2019-08-21, 1398/05/30

Trial completion date

2019-11-21, 1398/08/30

Scientific title

The effect of maternal empowerment program on the colostomy complications in infants and tolerance of mother's distress

Public title

The effect of maternal empowerment program on the colostomy complications in infants and tolerance of mother's distress

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

for Infant: Infant Age 0 to 90 Days - Infant's Clinical Stability (Including Heart Rate and Breathing) - Need for Colostomy in Treatment - No Other Abnormalities (like Metabolic Disorders, Immune Deficiency and Chemotherapy Neonates PerTerm and Term - Infant's Clinical Stability (Including Heart Rate and Breathing Need for Colostomy in Treatment No Other Abnormalities (like Metabolic Disorders, Immune Deficiency and Chemotherapy For the mother: consent to participate in the study No psychiatric disorders (depression and hoarseness based on physical symptoms and confession of the spouse or accompanying health and illness status) based on self-reported and physical disability or disabling illnesses affecting infant care) Is not addicted to self-expression. Has reading and writing skills.

Exclusion criteria:

Physical and mental disorders affecting the care of the baby During the study, according to the physician, a Diagnosis of one of the metabolic diseases, Immune deficiency or chemotherapeutic defects, etc. unwillingness to continue working, not attending one of the three training sessions, not attending to assess the complications of the exclusion criteria for the infant: neonatal death a Diagnosis of one of the metabolic diseases, Immune deficiency or chemotherapeutic defects, etc.

Age

From **1 day** old to **90 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Balanced Block Randomization: Randomized allocation was used to allocate children to the intervention and control groups using the 4-way blocking method (AAAA) and (BBBB); they were selected by lottery for the first intervention or control group and the rest were randomized. In order to prevent information leakage, the next block was started after the last unit block was cleared.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

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School of Nursing and Midwifery -Daneshgah St

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Razavi Khorasan

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Approval date

2019-03-05, 1397/12/14

Ethics committee reference number

IR.MUMS.NURSE.REC.1398.003

Health conditions studied**1****Description of health condition studied**

Complications of the colostomy

ICD-10 code

Z93.3

ICD-10 code description

Colostomy status

Primary outcomes**1****Description**

Complications Ostomy -

Timepoint

For complications of ostomy, one, two, three months after ostomy, empowerment

Method of measurement

Dermatologic distress tolerance questionnaire

2**Description**

Tolerance of mother distress

Timepoint

Before intervention - Immediately after intervention - One and two months after intervention

Method of measurement

DTS distress tolerance questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:: Three 45 minute sessions of mother empowerment for neonatal colostomy including: first session of maternal information, gastrointestinal complications and complications - second session of correct prenatal care and colostomy - third session including evaluation of maternal performance in neonatal care
Practical control group: Only receive the first session of maternal information assessment training, familiarity with the gastrointestinal tract and the causes of colostomy and routine care.

Category

Prevention

2

Description

Control group: The control group will receive the first training session on familiarity with gastrointestinal tract, colostomy and complications of colostomy and will receive routine care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Sheikh Children's Hospital

Full name of responsible person

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Recruitment center

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Sponsors / Funding sources

1

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Name of organization / entity

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Grant name

Vice chancellor for research, Mashhad University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Behnam Vashani Hamid Reza

Position

Assistant Professor of Pediatrics, School of Nursing and Midwifery, Mashhad University of Medical Sc

Latest degree

Master

Other areas of specialty/work

Nursery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available